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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,862	01/15/2004	Douglas H. Irish	DKP 0101 PUS1	4622
22045 7590 05/30/2008 BROOKS KUSHMAN P.C. 1000 TOWN CENTER TWENTY-SECOND FLOOR SOUTHFIELD, MI 48075				
EXAMINER VU, QUYNH-NHU HOANG				
ART UNIT		PAPER NUMBER		
3763				
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05/30/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/757,862

**Applicant(s)**

IRISH, DOUGLAS H.

**Examiner**

QUYNH-NHU H. VU

**Art Unit**

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3-15, 17-20 and 22-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-15, 17-20, 22-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Response to Amendment*

Amendment filed on 1/24/07 has been entered.

Claims 1, 3-15, 17-20, 22-30 are present for examination.

Applicant's arguments filed on 1/24/07 have been fully considered but are not persuasive.

Therefore, claims 1, 3-15, 17-20, 22-30 are rejected in the new ground rejections.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-15, and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lessing, Jr (US 5,688,248) in view of Lloyd et al. (US 3,572,340) and Miller et al. (US 5,671,983).

Lessing discloses a device comprising a pouch (15) having an interior formed by connected front and back sides, the front side of the pouch having a first exposable opening (21), the back side of the pouch having a second exposable opening 24; a catheter apparatus 25 having sleeve connected to the first opening. Lessing discloses a dialysis catheter device 25. Therefore, the device/catheter apparatus 25 inherently obvious including a fill-drain tube also. However, Lessing silent the sleeve for fill-drain tube and the catheter; an internally disposed hand covering element in communication with the exterior of the pouch, or peel away seals, adhesive on the back of the pouch.

Lloyd discloses a suction drainage device, similar device with Lessing, including a sleeve 16 covers a tube 15 for fluid-tight relationship.

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It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Lessing Jr. by adding a sleeve covers the fluid-drain tube and catheter tube, as taught by Lloyd, in order to provide the fluid tight relationship, prevent leaking and growing of bacteria.

Miller discloses a similar device with an internally disposed mittens covering element in communication with the exterior of the pouch (see fig. 5) and peel away seals (638) on the back of the pouch.

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Lessing Jr. by adding the mittens, and peel away seals of the type taught by Miller et al, in order to provide a sterile environment.

Furthermore as to claims 13, 17 and 19, it would have been an obvious matter of design choice to include plastic on the pouch as this is a common material used in for catheter and color the pouch, drain tube, catheter sleeve and the hand covering element a different color as the applicant has not disclosed that altering the color solves any stated problem and it appears that the invention would work equally well if the parts were the same color.

Claims 22-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lessing, Jr (US 5,688,248) in view of Lloyd et al. (US 3,572,340) and Miller et al. (US 5,671,983) and further in view of Miltzer (US 5,496,282).

As to claim 22, Leasing, Lloyd and Miller disclose the device as described above, but fail to disclose that the fill-drain tube in connected at a first end by a Y connection. Miltzer et al discloses a similar device with a Y-connector (see fig. 1).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Lessing in view of Miller by adding the Y- connector of the type taught by Miltzer et al in order to connect to both a fill source and drain receptacle.

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As to claims 23-30, Lessing Jr., Lloyd and Miller disclose the method using the device as described above, but fail to disclose the step of clamping the catheter with the catheter clamp prior to connecting the fill-drain tube and removing the clamp after connecting to the fill drain tube.

Miltzer et al discloses a similar device and method including the step of clamping the catheter with the catheter clamp prior to connecting the fill-drain tube and removing the clamp after connecting to the fill drain tube (col. 5 line 5).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the method of Lessing Jr. in view of Miller et al by adding the step of clamping the tube as taught by Miltzer et al, in order to maintain sterility of the device components.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-15, 17-20, 22-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent Nos. 6,682,507.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the device and method of instant claims are fully disclosed and covered by the claims in the patent.

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***Response to Arguments***

Applicant's arguments with respect to claims 1, 3-15 and 17-30 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu  
Examiner  
Art Unit 3763